# REMARKS/ARGUMENTS

The Patent Office examines and rejects claims 1-16, 49-5, 62-79 and 81-87. Applicants amend claims 1, 49, 54 and 85-57. Applicants submit that no new matter is added therein as amendments to the claims are supported at least at paragraphs [0004], [0006], [0007] and Figures 1A, 1B and 4 of the application. Amendments to the claims to require that a plurality of the imaged markers are implanted completely internally, are supported at least at Figs. 1A and B and paragraphs 53-54 of the application.

Hence, Applicants respectfully request reconsideration of the pending claims in view of the remarks herein.

## Double Patenting

Applicants appreciate the Patent Office's provisional obviousness-type double patenting rejection of claims 1-16, 49-58, 62-79 and 81-84 provisionally rejected over claims 15-21, 24, 31-43 and 53-60 of co-pending U.S. Patent Application No. 10/664,308. Applicants will address the provisional double patenting on issuance of one of the involved patents.

## Claims Rejected Under 35 U.S.C. §103

The Patent Office rejects claims 1-3, 5-7, 13-14, 16, 49-58, 62, 76-77, 82, 84 and 87 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman). Claims 4 and 83 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claim 1 above, and further in view of U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray). Claims 8-9, 12, 78-79 and 81 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 6-7 above, and further in view of U.S. Patent No. 5,757,953 to Jang (Jang). Claims 10-11 are rejected under 35 U.S.C. §103(a) as unpatentable over Mate in view of Cosman and Jang as applied to claim 8 above and further in view of U.S. Patent No. 5,446,548 to Gerig et al. (Gerig). Claims 15, 63-72 and 74 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 6,073,044 to Fitzpatrick et al.

(Fitzpatrick). Claims 73 and 75 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman and Fitzpatrick as applied to claim 64 above, and further in view of US Patent No. 5,622,187 to Carol ("Carol"). Claims 85-86 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 1 and 58 above, and further in view of U.S. Patent No. 6,398,710 to Ishikawa et al. ("Ishikawa"). For a claim to be obvious every limitation of that claim must be taught by at least one property combined reference.

Applicants respectfully disagree with the rejection above and submit that independent claim 1 is patentable over the cited references for at least the reason that none of the references teach imaging a plurality of markers in a first and in a different second imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; and determining first coordinates and second coordinates and internal to the body, wherein at least a plurality of said markers are implanted in soft tissue of the body, as required by claim 1.

Mate teaches a primary purpose of allowing target 12 to be accurately positioned at a treatment machine isocenter by acceptably aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39). Mate teaches that imaging data from a CT, MRI, or ultra-sound imaging system may be used to provide a simulated model of the target, the markers, and the target isocenter during simulation (see paragraph 60) and that images of tumor 90 and markers 30 can be obtained by CT, MRI, ultra-sound or other imaging techniques to monitor the status of the target, such as a tumor and the like, in a patients body 14 over time (see paragraph 62). However, as noted on page 4 of the current Office Action, Mate fails to show using more than one imaging modality to determine coordinates of markers relative to beam isocenters, as required by claim 1. Instead, Mate teaches that markers can be located by exciting markers 30 with excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying low energy radial-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). Thus, Mate does not teach imaging a plurality of markers in a first and in a different second imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; and determining first coordinates and second coordinates and internal to the

body, wherein at least a plurality of said markers are implanted in soft tissue of the body, as required by claim 1.

Moreover, Mate fails to teach determining first and second coordinates relative to beam isocenters; correlating the second coordinates with the first coordinates; and calculating an offset between the first coordinates and the second coordinates for at least one of the plurality of markers as required by claim 3. As noted on page 4 of the current Office Action, Mate fails to show using more than one imaging modality to determine coordinates of markers beam isocenters. Next, Mate fails to teach the false markers of claim 12; the gantries of claim 60; or the limitations of claims 85-86.

Next, the primary purpose and principle of operation of Cosman is to coordinate external markers for external treatment apparatus to specific targets within the body (see paragraphs 8 and 9). The camera of Cosman images the external markers relative to photons reflected from the external markers (see paragraphs 31 and 102). For example, Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of external marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers are geometric objects to indicate positions of locations that are visible to a camera (see paragraph [0063]). Cosman also mentions that refinement of internal target positioning can be achieved by x-ray imaging components 80 and 81 aligned on axes 14 and 12 to determine a digital image of x-ray through a patients body (see paragraph 67) and that a portal imager 85 can provide a digital image from high energy x-rays emitted from collimator 5 (see paragraph 67). Thus, diagnostic x-rays from machines 80 and 81 or high energy x-rays for portal imaging can be used to visualize markers implanted in bones or tissue within the patient prior to treating (see paragraph 67). However, Cosman does not teach or enable determining coordinates of the same set of markers relative to a first and second beam isocenter as required by claim 1. Instead, Cosman only provides coordinating the location of an internal target and externally visible fiducial markers that can be scanned by a camera (see paragraphs 24, 29-34, 39-41, 52, 61 and 68). For example, the primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target with the isocenter of a beam (see paragraphs

[0064]-[0066] and Figure 3C). Thus, Cosman can not teach imaging a plurality of markers in a first and in a different second imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; and determining first coordinates and second coordinates and internal to the body, wherein at least a plurality of said markers are implanted in soft tissue of the body, as required by claim 1.

Moreover, Cosman does not teach determining coordinates of the same set of completely internal markers relative to a first and second beam isocenter; correlating the second coordinates with the first coordinates; and calculating an offset between the first coordinates and the second coordinates for at least one of the plurality of markers as required by claim 3. Next, Cosman fails to teach the false markers of claim 12; the gantries of claim 60; or measuring radiation received by the markers of additional claims 85-86. For example, Cosman does not provide enough detail in paragraph 67 to enable any of the above noted claims.

Finally, Applicants do not believe that the combination of Cosman with Mate to teach the above limitations of the claims is proper. As noted, the primary purpose of Mate is to image a target and markers 30 around the target so that during treatment, the markers can be excited with excitation source 32 to resonate at a low energy radial-frequency magnetic signal measurable from outside the body, in order to ensure proper positioning of the target (see Mate paragraphs 35-39 and 60-62). Thus, there is no need or motivation for a practitioner to add a second imaging modality to Mate. Moreover, a practitioner would not attempt to combine the external fiducial markers (e.g., markers 20, 21, 23 and 24) or implanted markers mentioned in Cosman (see Cosman paragraphs 31 and 67) with Mate because (1) Mate does not require surface mounted markers (see paragraphs 65-68) and does not require additional internal markers in addition to markers 30 (see Mate paragraphs 60-62). Next, even if Cosman were combined with Mate, the combination does not enable determining first and second coordinates of the markers relative to a first and second beam, as required by claim 1 because neither reference coordinates images from two beams of two different imaging modes.

Applicants also disagree with the rejection above of independent claims 49 and 54 for at least the reason that the cited references do not teach imaging markers in a first and second imaging modality, wherein at least a plurality of the markers are implanted completely internally

in a body; and determining first coordinates and second coordinates and internal to the body, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the different second beam isocenter is a high energy beam of radiation of a treatment machine, as required by amended claims 49 and 54.

Mate teaches a primary purpose of allowing target 12 to be accurately positioned at a treatment machine isocenter by acceptably aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39). Mate teaches that imaging data from a CT, MRI, or ultra-sound imaging system may be used to provide a simulated model of the target, the markers, and the target isocenter during simulation (see paragraph 60) and that images of tumor 90 and markers 30 can be obtained by CT, MRI, ultra-sound or other imaging techniques to monitor the status of the target, such as a tumor and the like, in a patients body 14 over time (see paragraph 62). However, as noted on page 4 of the current Office Action, Mate fails to show using more than one imaging modality to determine coordinates of markers relative to beam isocenters, as required by claims 49 and 54. Instead, Mate teaches that markers can be located by exciting markers 30 with excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying low energy radial-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). Thus, Mate does not teach imaging a plurality of markers in a first and in a different second imaging modality and internal to a body, wherein at least a plurality of the markers are implanted in a body; and determining first coordinates and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine as required by claims 49 and 54.

The primary purpose and principle of operation of Cosman is to coordinate external markers for external treatment apparatus to specific targets within the body (see paragraphs 8 and 9). The camera of Cosman images the external markers relative to photons reflected from the external markers (see paragraphs 31 and 102). For example, Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of

external marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers are geometric objects to indicate positions of locations that are visible to a camera (see paragraph [0063]). Cosman also mentions that refinement of internal target positioning can be achieved by x-ray imaging components 80 and 81 aligned on axes 14 and 12 to determine a digital image of x-ray through a patients body (see paragraph 67) and that a portal imager 85 can provide a digital image from high energy x-rays emitted from collimator 5 (see paragraph 67). Thus, diagnostic x-rays from machines 80 and 81 or high energy x-rays for portal imaging can be used to visualize markers implanted in bones or tissue within the patient prior to treating (see paragraph 67). However, Cosman does not teach or enable determining coordinates of the same set of completely internal markers relative to a first and second beam isocenter as required by claims 49 and 54. Instead, Cosman only provides coordinating the location of externally visible fiducial markers that can be scanned by a camera (see paragraphs 24, 29-34, 39-41, 52, 61 and 68). For example, the primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target with the isocenter of a beam (see paragraphs [0064]-[0066] and Figure 3C). However, Cosman does not teach determining first coordinates and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the different second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine as required by claims 49 and 54 because Cosman does not coordinate images from the same set of completely internal markers from two beams of two different imaging modes.

In addition, by imaging markers wherein at least a plurality of the markers are residing completely internally in a body in two modalities as required by the independent claims, some embodiments described in the specification, for example, without limitation thereto, may provide one or more of: (1) the benefit of measuring radiation received by internal markers near anatomical landmarks to extrapolate the amount of radiation delivered to anatomical landmarks to minimize damage to such areas from treatment (see paragraph [0043] of the Application; and claims 85-86); (2) the benefit of determining more accurate positions of soft tissue internal body areas having internal markers situated therein to ensure that a target volume (e.g., tumor)

receives sufficient radiation and that injury to the surrounding and adjacent soft tissue non-target volumes (e.g., healthy tissue) is minimized (see paragraphs [0055] and [0074] of the Application; and claims 1 and 56-57); (3) the benefit of imaging internal markers left in soft tissue of the body to provide more accurate positioning of a target volume during multiple treatment sessions to account for daily treatment machine setup variation and various types of soft tissue and/or organ movement (see paragraph [0078] of the Application; and claims 1 and 56-57); and/or (4) the benefit of imaging in an x-ray imaging modality, wherein the first beam isocenter is an isocenter of an x-ray image system, and imaging in a second x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine (see paragraphs [0043], [0048] and [0055]-[0057] and [0074] of the Application; and claims 49 and 54. Thus, the invention may have any one or any combination of the foregoing benefits. However, the references do not contemplate or enable such benefits.

In addition to being dependent upon allowable base claim 1, Applicants disagree with the rejection above of claims 85-86 for at least the reason that the cited references do not teach measuring radiation received by the implanted completely internally markers having coordinates determined relative to a first and second beam isocenter, as required by claims 85 and 86. As noted by the Patent Office, neither Mate nor Cosman teaches such limitations. Moreover, Ishikawa teaches using markers that communicate using radio frequency transmission signals received by receivers 126 and 128 (see col. 4, lines 25-50, claim 4 and Figure 2), but does not teach the above-noted limitations.

Claims 85 and 86 must be considered in their entirety, including the fact that they require the implanted completely internally markers that perform the measuring radiation received during a treatment session be the same implanted completely internally markers that are imaged in the two imaging modalities, and for which coordinates are determined relative to a first and second beam isocenter. Hence, none of the references teach the above noted limitations of claims 85 and 86. Moreover, Applicants assert that the combination of Ishikawa with Mate or Cosman is improper since the primary purpose of the markers in Mate is to be excitable by excitation source 32 so that they provide a low energy radial-frequency magnetic signal measurable from outside the body (see paragraph 36). Thus, a practitioner would not be motivated to, and would not be able without undue experimentation to combine the magnetic

signal markers of Mate with the radio-frequency markers of Ishikawa because the magnetic and radio-frequency signal would interfere with each other based on electromagnetic wave principles of physics. Moreover, a practitioner would not be motivated to, and would not be able without undue experimentation to combine the external fiducial markers that may be LED emitters, reflectors of light, reflecting spheres...of Cosman (see paragraph 31) with the radio-frequency markers of Ishikawa. Finally, the motivation cited by the Patent Office for this combination of references appears to be gleaned only from Applicants claims.

Any dependent claims not mentioned above are patentable over the cited references for at least the reasons provided above of their base claims as well as for additional limitations of dependent claims.

Hence, Applicants respectfully request withdrawal of all the rejections above for all of the claims.

## CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Jessica Huester — Date: 2009-10-27